

NOV 15 2005

510(k) Summary

Submitted By: BioPro
17 17th Street
Port Huron, MI 48060

Contact: Dave Mrak
(810) 982-7777 (ext.101)
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Device Information:

Proprietary Name: BioPro Modular Thumb Implant

Common Name: Prosthesis, Thumb, Hemi, Metacarpal

Classification Name:

Biopro Modular Thumb Implant

The Biopro Modular Thumb prosthesis has been designed for dysfunction associated with advanced degenerative or rheumatoid arthritis of the thumb carpo-metacarpal joint. The implant is modular and is made available in 3 combinations a neutral a +2mm and +4mm length of 4 head dimensions (12mm-15mm in one millimeter increments) and 4 stem sizes (7.5mm, 8.5mm, 10.0mm and 11.0mm),. The tri-flanged and partially porecoated stem provides an immobile press-fitted fixation within the medullary canal. The varus angle of the implant assures the implant remains in contact with the trapezium throughout range of motion, reducing the risk for dislocation. The stem is anatomically configured in the sagittal plane to fit the curvature of the metacarpal canal. The head is slightly medialized and is at a 15-20 degree varus angle. The head articulates against the trapezium after a spherical concavity is burred into the trapezium to match the radius of the head.

The Biopro devices are intended to resurface the joint in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis, or post fracture deformation or bone loss which presents themselves as either a painful, instable thumb or a thumb with limited range of motion. These indications are the same as those for the predicated device, the Swanson Titanium Condylar Implant. The components function the same, they both resurface the joint to provide pain relief and increase motion in the joint. However, the Biopro implant has interchangeable heads. This allows for flexibility during surgery. Combinations of the heads and stems can be created to match the patients anatomy. There are 48 possible combinations of head and stem assemblies. The modularity allows for better matching to the metacarpal and trapezium for size, it also allows the surgeon to properly tension the joint due to the multiple head lengths, reducing the risk of dislocation and requiring less remodeling of the patients anatomy.

The implant is sold in a sterile condition. The sterilization method used is Ethylene Oxide.

Substantial Equivalence:

The Biopro Modular Thumb implant is claimed to be substantially equivalent to the Swanson Titanium Condylar Implant (K864488). Both devices resurface the proximal end of the first metacarpal. They have intramedullary stems with a head that acts as a joint spacer. The heads articulate against the distal end of the trapezium which is remodeled to contain the shape of the implant head. The Biopro device is a two piece design and the Swanson is a one piece design. The Biopro device is made of cobalt chrome while the Swanson device is made from unalloyed titanium.

The differences between the subject device and the predicate device follow: First the head diameters are larger for the BIOPRO device than the Swanson components. This provides a wider range of motion for the joint. With the Biopro device, the remodeling of the trapezium is continued into the second metacarpal to prevent impingement of the implant against the bone. Also the cross-section of the stems are different. Both are intended to prevent rotation of the device, however, the Swanson stem is square while the Biopro stem is tri-flanged. The Biopro stem is also anatomically shaped to fit the curvature of the medullary canal in the sagittal plane



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

David Mrak
Director of Product Development
BioPro, Inc.
17 17th Street
Port Huron, Michigan 48060

Re: K052596

Trade/Device Name: BioPro Modular Thumb Implant
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: II
Product Code: KYI
Dated: August 2, 2005
Received: September 21, 2005

Dear Mr. Mrak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052596

Device Name: Biopro Modular Thumb

Indications For Use:

1. Rheumatoid arthritis
2. Traumatic arthritis
3. Osteoarthritis
4. Post Fracture deformation or bone loss


Prescription Use xxxxx
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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